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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,751	07/26/2000	Mary M. Morris	11738.00002	8051

22908 7590 01/22/2004

BANNER & WITCOFF, LTD.
TEN SOUTH WACKER DRIVE
SUITE 3000
CHICAGO, IL 60606

EXAMINER	
WILLIAMS, CATHERINE SERKE	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/625,751	Applicant(s) MORRIS ET AL.	
	Examiner Catherine S. Williams	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31-42* is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-6, 8, 11-12, 16-17, 19-21, 23-24 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker et al (US Pat# 5,462,521).

Brucker discloses a perfusion tip for a catheter that includes a proximal end having an opening, a distal end defining at least one opening, a drug delivery segment with a longitudinal axis and a length of about 0.1-1.0 cm (see figure 9). The segment has an outside surface with an outside diameter of about 0.64 inches and an inside surface with an inside diameter of about 0.32 inches. The segment has non-tapered tubes having a length of about 0.16 inches that extend radially from the inside surface of the outside surface where the ratio of the length of the tubes to the diameter of the tubes is about 5-25. The segment defines a lumen along its longitudinal axis. The tubes are arranged in a row parallel with the longitudinal axis of the segment and there is at least a proximal tube a middle tube and a distal tube within the row. The tubes are equally spaced from each other in the row. The distance from the proximal tube to the distal tube in the row is about 5.5 mm and the distance from the middle tube to the distal end of the lumen of the segment is about 5 mm. The tubes have substantially the same diameters and range in diameter size from about 0.001 to 0.005 inches. The segment has ring bands (30) that may be made from platinum or stainless steel. The catheter is capable of being implantable for more than 24 hours,

and is capable of providing fluid containing a therapeutic drug to the target site at a rate of about 2 microliter/hour to 10 microliters/minute. The fluid is considered a therapeutic drug in that it regulates the impedance rise of tissue in contact with the catheter tip and a fluid source is considered inherent for the device to function as disclosed.

Brucker meets the claim limitations as described above but fails to show the tip being grooveless. However, other embodiments disclosed by Brucker (see figures 6,7 and 10) have grooveless surfaces.

At the time of the invention, it would have been obvious to incorporate the grooveless outer surface of the tips of figures 6, 7 or 10 into the embodiment of figure 9. The motivation for making the substitution would have been to provide a smooth tip surface in order to prevent tissue from catching, snagging or ripping if brushed by the grooved surface.

Claims 4, 7, 9-10, 12-15, 18, 25-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker et al.

Regarding claim 25, Brucker meets the claim limitations as described above but fails to include a method including forming the segment, forming the tubes, providing a therapeutic compound and distributing the compound. The fluid is considered a therapeutic drug in that it regulates the impedance rise of tissue in contact with the catheter tip. At the time of the invention, it would have been obvious to have carried out the method steps as described above since the steps would have been required to assemble and use the device.

Regarding claims 4 and 27, Brucker meets the claim limitations as described above but fails to include laser or ion beam drilled tubes. At the time of the invention, it would have been

obvious to manufacture the tubes using laser or ion beam drilling since it is well known in the art and is used in order to provide enhanced accuracy regarding manufacturing tolerances.

Regarding claims 7, 10, 13 and 18, Brucker meets the claim limitations as described above but fails to disclose the number of tubes as claimed. At the time of the invention, it would have been obvious to have the number of tubes as claimed since perfusion cannula are well known in the art to have a variety of perfusion ports (tubes) depending on the size of the tissue being treated. Adding more tubes to the invention of Brucker would have been done in order to provide greater perfusion to a larger tissue bed.

Regarding claims 9-10, 12 and 14-15, Brucker meets the claim limitations as described above but fails to disclose 4 or 8 rows. At the time of the invention, it would have been obvious to have the number of rows as claimed since perfusion cannula are well known in the art to have a variety of perfusion port arrangements depending on the size of the tissue being treated. Adding more rows to the invention of Brucker would have been done in order to provide greater perfusion to a larger tissue bed.

Claims 22 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker in view of Lindsay et al (US Pat# 4,863,441).

Brucker meets the claim limitations as described above but fails to include the tubes being tapered.

Lindsay discloses a venous return cannula that has ports at the distal end that are chamfered (tapered) in order to provide resistance to kinking at the tip.

At the time of the invention, it would have been obvious to incorporate the teaching of chamfered (tapered) ports or tubes of Lindsay into the invention of Brucker in order to provide enhanced resistance to bending.

Allowable Subject Matter

Claims 31-42 are allowed.

Response to Arguments

In response to applicant's argument regarding Brucker ('521) that there is no suggestion to modify figure #9 with the teaching of figure 6, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation comes from general knowledge available to one skilled in the art. It is well known in the catheter art that irregular surfaces on a catheter tip can injure tissue during the insertion of the catheter into the body. Many patents are devoted to the design of smooth catheter tip structures to prevent tissue injury during insertion. The embodiments of figures 6 and 9 are very similar. The only differences are that Figure 9 has grooves and a lumen that opens at the distal end of the catheter. It would have been obvious to combine the embodiments to elicit a catheter having a smooth outer surface to

enhance the safety to the patient while maintaining the lumen opening at the distal end of the catheter (which is not taught by Figure 6).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke Williams CSW.
January 12, 2004

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
GROUP 3700